Previous claims 1 - 22 and 38 - 41:

1. An improved method of primary hormonal treatment with lesser or no toxic effect as primary treatment of early stage, low and intermediate risk prostate cancer and said primary hormonal treatment comprising of prostatic implants of steroid hormones, or its synthetic derivatives in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to prostate for longer periods and maintaining said formulation's serum level sufficient to effect suppression of androgen synthesis but low enough to minimize or to eliminate systemic toxicity.

2. A method according to claim 1, wherein said primary hormonal implant treatment of early stage, low and intermediate risk prostate cancer as an alternative to surgery and radiation therapy and the surgery or radiation therapy is reserved for those patients failing to said primary hormonal treatment

3. A method according to claim 1 further comprising release of said hormonal compositions to prostate for extended periods by diffusion and biodegradation from said prostatic implants in sufficient amounts to saturate the binding sites for said drug compositions in prostate and to

low nadir value of 0.1 to 1 ng per ml as with post radiation therapy PSA values.

4. A method according to claim 1further comprising systemic maintenance of said drug compositions for extended periods by diffusion and biodegradation from said prostatic implants at an amount effective to suppress testicular and adrenal androgen synthesis with minimum or no systemic toxicity than if said drug compositions were administered orally or by intravenous, intramuscular or subcutaneous injections at much higher doses.

5. A method of claim 1 wherein said implants comprising of hormonally effective compositions selected from the natural or synthetic derivatives from the groups consisting of estrogens, progesterones, corticosteroids, from the anti-androgen groups consisting of flutamide, bicalutamide and nilutamide.

6. A method according to claim 1 wherein said prostatic implants of said drug compositions are made as separate or in combination thereof.

7. The method of claim 1 wherein said prostatic implants are made as biodegradable fused combinations of said therapeutic drug compositions

and a lipoid carrier and said fused implants containing a single or multiples of said drug formulations for their slow release direct to prostate.

8. A method according to claim 1 wherein said prostatic implants are made of Silastic capsules containing said therapeutic drug compositions as separate or in combination thereof for said formulation's slow release direct to prostate.

9. The method of claim 1 wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions as separate or as in combination thereof for prostatic injection as slow release implant.

10. The method of claim 9, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in sterile liquid medium in sterile syringe for direct prostatic injection as slow release implant.

11. The method of claim 9, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in a mixture of sterile liquid mediums like normal saline, a local anesthetic

and ethanol in a sterile syringe for direct prostatic injection as chelating slow release formulations when it comes in contact with tissue.

12.A method of claim 1, wherein implanting said implant compositions comprises of retropubic implants, trans perennial implant, trans rectal ultrasound based visualization of the prostate and implantation, computed tomography based visualization of prostate and implantation or by surgically exposing and free hand implanting.

13.The method of claim 1 wherein said prostatic implants are selected from readily available commercial pharmaceutical implant preparations of androgen suppressive steroid hormones or their derivatives and said implants containing a single or multiples of said drug formulations for their slow release direct to the prostate.

14. An improved method of concomitant hormonal and radiation treatment of prostate cancer and said hormonal treatment comprising of prostatic implants of steroid hormones in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to the prostate during the radiation therapy and afterwards for longer periods and maintaining said formulation's serum level sufficient to effect suppression of androgen synthesis but low enough to minimize or to eliminate their toxicity.

15. An improved method of concomitant hormonal and radiation treatment of prostate cancer according to claim 14, wherein said continued slow release of hormonal composition directly to the prostate during the interstitial radioactive seeds implants and afterwards for longer periods and maintaining said hormonal formulation's serum level sufficient to effect suppression of androgen synthesis but low enough to minimize or to eliminate their toxicity.

16. An improved method of concomitant hormonal and radiation treatment of prostate cancer according to claim 14, wherein said hormonal implants to prostate is performed concomitantly with the radioactive implants to improve cure and convenience to patient than when they are implanted separately.

17. A prostatic, subcutaneous or intramuscular implant method for hormonal treatment of prostate cancer for improved tumor control and less toxicity from hormonal treatment than by administering said hormonal compositions by oral, or intravenous routes and said hormonal treatment comprising of prostatic, subcutaneous or intramuscular implants of steroid hormones and or their synthetic derivatives in one or more slow release formulations.

18. A method of claim 17, wherein said prostatic, subcutaneous or intramuscular implants methods comprising single or synergetic combination of hormonally and cytotoxically effective compositions selected from natural or synthetic derivatives from the groups consisting of estrogens, progesterones, corticosteroids and from the anti-androgen groups consisting of flutamide, bicalutamide and nilutamide and they are fused with a lipoid carrier or encapsulated in Silastic capsules or formulated as injectable microcapsules as suitable slow-release prostatic, subcutaneous or intramuscular implant.

19.A method of claim 17, wherein said hormonally and cytotoxically effective compositions are continuously released at relatively constant rates to the systemic circulation by diffusion and biodegradation.

20.A method of claim 17, wherein said implants providing effective tumor control by suppression of hypothalamic LHRH and pituitary LH and FSH secretion and thereby suppression of testicular and adrenal androgen synthesis and or by their direct cytotoxic actions and said tumor control is evidenced by the decrease of serum PSA to a low nadir value of less than 1 ng per ml and serum acid phosphatase to less than 0.8 international unit, its upper limit of normal value.

21. A method of claim 17, wherein said slow-release subcutaneous or intramuscular implant for treating prostate cancer and providing minimum or no toxicity as compared to when said drug compositions were frequently administered orally or by intravenous injections at much higher doses to achieve the same rate of tumor control.

22. A method of claim 17, wherein when said implants are made as direct prostatic implants to reach said drug composition's high concentrations in the prostate and thereby to improve tumor control.

38. A prostatic, subcutaneous or intramuscular slow-release hormonal implant method and products comprising single or synergetic combination of hormonally and cytotoxically effective compositions selected from the natural or synthetic derivatives from the groups consisting of estrogens, progesterones, corticosteroids, from the anti-androgen groups consisting of flutamide, bicalutamide and nilutamide and they are fused with a lipoid carrier or encapsulated in Silastic capsules or formulated as injectable microcapsules as suitable slow-release prostatic, subcutaneous or intramuscular implantation and implanting said products for the treatment of early and advanced stage prostate cancers or as hormonal treatment combined with radiation.

39. A method and product of claim 38, wherein said tumor control is evidenced by tumor regression and the return of pre-treatment elevated serum PSA to a low nadir value of less than 1 ng per ml and serum acid phosphatase to less than 0.8 international unit, its upper normal limit value.

40. A method and product of claim 38, wherein said hormone implant treatment as lesser-cost androgen suppressive treatment.

41. A method and product of claim 38, wherein said slow-release hormone implant treatment as hormonal prophylaxis against developing the prostate cancer in high risk group of men by slow release of androgen suppressive steroids from said hormone implants to the prostate in higher concentrations and their serum concentrations kept as low as just sufficient to suppress the androgen synthesis with none or minimal systemic toxicity and to follow up of any evidence of potential tumor development by periodic estimations of serum PSA and acid phosphatase which under said treatment will be at a low nadir value of less than 1 ng per ml for PSA and less than 0.8 international unit for serum acid phosphatase.

In the claims:

Clean version incorporating all changes

Claims replacing the original claims 1 - 22 and 38 – 41

1. A method of minimal or no toxic primary hormonal treatment of early stage, low and intermediate risk prostate cancer and said primary hormonal treatment comprising of prostatic implants of a natural or synthetic estrogens, antiandrogens and their derivatives as fused with a lipoid carrier or as encapsulated in Silastic capsules or as injectable microcapsules and are suitable for prostatic implantation such that said hormonally and cytotoxically effective compositions are continuously released at rates of 50 to 100 μg per day directly to the prostate and a lower concentration of 250 –500 pg. to systemic circulation that is effective to suppress the testicular and adrenal androgen synthesis by inhibition of LHRH, FSH and LH secretions and to minimize the systemic toxicity caused by administration of said drugs by oral,

43. A method according to claim 42, wherein said minimal or no toxic primary hormonal implant treatment of early stage, low and intermediate risk prostate cancer with natural or synthetic estrogens and antiandrogens and their derivatives as fused with a lipoid carrier or as encapsulated in Silastic capsules or as injectable microcapsules as an alternative to surgery and radiation therapy and to minimize said drug's toxicity associated with their oral, subcutaneous, intramuscular or intravenous administration at much higher doses ranging from 1 to 750 mg .

44. A method of minimal or no toxic hormonal treatment of prostate cancer according to claim 42, further comprising release of 50 – 100 μg of said hormonal compositions to prostate for extended periods of one to five years by diffusion and biodegradation of said prostatic hormonal implants to saturate the said drug's binding sites in prostate and to exert its maximum tumor control activity and to maintain the biochemical tumor control as evidenced by low serum PSA level as comparable to a nadir value of 0.1 to 1 ng per ml and as comparable with post radiation therapy PSA values.

45. A method of minimal or no toxic hormonal treatment of prostate cancer according to claim 42, further comprising systemic maintenance of said drug compositions for extended periods of one to five years at the prostatic tumor sites to inhibit the tumor growth by diffusion and biodegradation of said prostatic implants and release of said hormonal compositions at a range of 250

- 500 pg. systemically to inhibit the secretion of LHRH, FSH and LH and thereby to suppress testicular and adrenal androgen synthesis to deprive the tumor from androgens and thereby its androgen dependent tumor growth and to minimize the systemic toxicity caused by administration of said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 750 mg to treat prostate cancer.

46. A method of minimal or no toxic hormonal treatment of prostate cancer of claim 42, wherein said implants comprising of hormonally effective compositions selected from the natural or synthetic derivatives from the group consisting of DES, estradiol 17-β, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine, and corticosteroids dependent tumor growth and to minimize the systemic toxicity caused by administration said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 750 mg to treat prostate cancer.

47. A method of minimal or no toxic hormonal treatment of prostate cancer according to claims 42, wherein said prostatic implants of said drug compositions are made as single drug formulation from any one of the drugs from a group consisting of DES, estradiol 17-β, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine or two drugs formulations comprising of DES and prednisolone, DES and flutamide, DES and progesterone, estradiol 17-β and prednisolone, estradiol 17-β and

progesterone, estradiol 17-β and flutamide, iodoestradiol and prednisolone, iodoestradiol and flutamide, iodoestradiol and progesterone, estramustine and prednisolone, estramustine and flutamide and estramustine and progesterone or as synergetic three drugs formulations comprising of DES, prednisolone and flutamide, DES, flutamide and progesterone, estradiol 17-β, prednisolone and flutamide, estradiol 17-β, progesterone and flutamide, iodoestradiol, prednisolone and flutamide, iodoestradiol, progesterone and flutamide separate or in combination thereof.

48. The method of minimal or no toxic hormonal treatment of prostate cancer of claim 42, wherein said prostatic implants are made as biodegradable fused combinations of said therapeutic drug compositions and a lipoid carrier and said fused implants containing a single or multiples of said drug formulations for their slow release at a rate of 50 – 100 μg direct to prostate to inhibit hormone dependent tumor growth and to minimize the systemic toxicity caused by administration of higher doses of said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 750 mg to treat prostate cancer.

49. A method for minimal or no toxic effects of hormonal treatment of prostate cancer according to claim 42, wherein said prostatic implants are made of Silastic capsules containing said drug composition as single drug formulation made from any one of the drugs from a group consisting of DES, estradiol 17-

β, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine or two drugs formulations comprising of DES and prednisolone, DES and flutamide, DES and progesterone, estradiol 17-β and prednisolone, estradiol 17-β and progesterone, estradiol 17-β and flutamide, iodoestradiol and prednisolone, iodoestradiol and flutamide, iodoestradiol and progesterone, estramustine and prednisolone, estramustine and flutamide and estramustine and progesterone or as synergetic three drugs formulations comprising of DES, prednisolone and flutamide, DES, flutamide and progesterone, estradiol 17-β, prednisolone and flutamide, estradiol 17-β, progesterone and flutamide, iodoestradiol, prednisolone and flutamide, iodoestradiol, progesterone and flutamide separate or in combination thereof for said formulation's slow release at a rate of 50-100 μg direct to prostate.

50. A method for minimal or no toxic effects of hormonal treatment of prostate cancer of claim 42, wherein said prostatic implants are made as microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug composition as single drug formulation made from any one of the drugs from a group consisting of DES, estradiol 17-β, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine or two drugs formulations comprising of DES and prednisolone, DES and flutamide, DES and progesterone, estradiol 17-β and prednisolone, estradiol 17-β and progesterone, estradiol 17-β and flutamide, iodoestradiol and prednisolone, iodoestradiol and flutamide, iodoestradiol and progesterone, estramustine and

prednisolone, estramustine and flutamide and estramustine and progesterone or as synergetic three drugs formulations comprising of DES, prednisolone and flutamide, DES, flutamide and progesterone, estradiol 17-β, prednisolone and flutamide, estradiol 17-β, progesterone and flutamide, iodoestradiol, prednisolone and flutamide, iodoestradiol, progesterone and flutamide.

51. The method of minimal or no toxic hormonal treatment of prostate cancer of claim 50, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in sterile liquid medium in sterile syringe for direct prostatic injection as slow release implant.

52. The method of minimal or no toxic hormonal treatment of prostate cancer of claim 50, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in a mixture of sterile liquid mediums like normal saline, a local anesthetic and ethanol in a sterile syringe for direct prostatic injection as chelating slow release formulations when it comes in contact with tissue.

53. A method of minimal or no toxic hormonal treatment of prostate cancer of claim 42, wherein implanting said implant compositions comprises of retropubic implants, trans perennial implant, trans rectal ultrasound based

visualization of the prostate and implantation, computed tomography based visualization of prostate and implantation or by surgically exposing and free hand implanting.

54. The method of minimal or no toxic hormonal treatment of prostate cancer of claim 42, wherein said prostatic implants are selected from readily available commercial pharmaceutical implant preparations of androgen suppressive steroid hormones or their derivatives and said implants containing a single or multiples of said drug formulations for their slow release direct to the prostate.

55. A method of minimal or no toxic hormonal treatment combined with radiation therapy of prostate cancer by concomitant prostatic implants of slow-release single drug formulation made from any one of the drugs from a group consisting of DES, estradiol 17-β, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine or two drugs formulations comprising of DES and prednisolone, DES and flutamide, DES and progesterone, estradiol 17-β and prednisolone, estradiol 17-β and progesterone, estradiol 17-β and flutamide, iodoestradiol and prednisolone, iodoestradiol and flutamide, iodoestradiol and progesterone, estramustine and prednisolone, estramustine and flutamide and estramustine and progesterone or as synergetic three drugs formulations comprising of DES, prednisolone and flutamide, DES, flutamide and progesterone, estradiol 17-β, prednisolone and flutamide, estradiol 17-β, progesterone and flutamide, iodoestradiol,

prednisolone and flutamide, iodoestradiol, progesterone and flutamide and concomitant radiation treatment of prostate cancer and said drugs are released directly to prostate by diffusion and biodegradation of implant at a daily rate of 50 - 100 μg during the course of radiation therapy and afterwards for periods of one to five years and maintaining said formulation's serum level in the range of 250 to 500 pg. by systemic distribution of diffused hormones to effect suppression of androgen synthesis but low enough to minimize or to eliminate their systemic toxicity as an alternative to administration of said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 750 mg when concomitant administration of hormones and radiation is used to treat prostate cancer.

56. A method for minimal or no toxic hormonal treatment of prostate cancer combined with radiation therapy according to claim 55, wherein interstitial radiation therapy is combined with said continued slow release hormonal compositions directly to the prostate during the extended course of radiation by said interstitial radioactive seeds implants and afterwards for periods of one to five years and maintaining said formulation's serum level during these periods in the range of 250 to 500 pg. by systemic distribution of diffused hormones to effect suppression of androgen synthesis but low enough to minimize or to eliminate their systemic toxicity as an alternative to administration of said drugs by oral, subcutaneous, intramuscular or intravenous routs at much higher doses ranging from 1 to 750 mg when

concomitant administration of hormones and interstitial radiation is used to treat prostate cancer.

57. A method for minimal or no toxic hormonal treatment of prostate cancer combined with radiation therapy according to claim 55, wherein said hormonal implants to prostate is performed concomitantly with the radioactive implants to improve cure and convenience to patient than when they are implanted separately.

58. A prostatic implant method of hormones and its derivatives for their maximum local suppressive effects on prostatic tumor growth and minimal or no toxic effects from hormonal treatment of prostate cancer wherein said implants comprising of hormonally effective compositions selected from the group consisting of estradiol 17-β, DES, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine, and corticosteroids and implanted directly to the prostatic tumor for its tumor suppressive effects by constant release of said hormones directly to tumor by said implant's biodegradation and diffusion and to saturate the receptor binding sites in tumor cells for implanted hormones to induce its cytotoxic activity as an alternative to administration of higher doses ranging from 1 to 750 mg of said drugs by oral, subcutaneous, intramuscular or intravenous routs to treat prostate cancer.

59. A prostatic implant method of hormones and its derivatives of claim 58, wherein said prostatic implants containing estradiol 17-β, DES, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine, and corticosteroids to release its contents directly to prostatic tumor and to exerts its tumor suppressive and cytotoxic effects on tumor cells for tumor control.

60. A prostatic implant method of hormones and its derivatives of claim 58 for continuos daily hormonal treatment of prostate cancer by continuos daily release of hormonally and cytotoxically effective compositions to tumor site for extended periods of five years by diffusion and biodegradation of implanted compositions.

61. A prostatic implant method of hormones and its derivatives of claim 58, wherein said implants providing effective tumor control by continued saturation of hormone binding receptor sites in tumor by said hormones and deprivation of testicular and adrenal androgens that binds to prostate and accelerates prostatic tumor growth by suppression of hypothalamic LHRH and pituitary LH and FSH secretion and to monitor said tumor control by decreased serum PSA as monitored after alternative treatment of prostate cancer.

62. A prostatic implant method of hormones and its derivatives of claim 58, wherein said slow-release of hormones and its derivatives from said implants

to maintain a steady state cytotoxic effect on tumor cells by said implant's contents of estradiol 17-β, DES, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine, and corticosteroids that suppress tumor growth.

63. A prostatic implant method of hormones and its derivatives of claim 58, wherein said implants are made as direct prostatic implants that delivers said drug composition at high concentrations to local prostate cancer that suppresses local tumor growth and to control distant metastatic tumor growth by systemic distribution of said hormones by said implant's biodegradation and diffusion into systemic circulation and its binding to metastatic tumor cell.

64. A prostatic implant method and products of hormones and its derivatives for suppression of local tumor growth by hormones and its derivatives with minimum or no toxic effects from hormonal treatment of prostate cancer wherein said implants containing hormonally effective compositions selected from the group consisting of estradiol 17-β, DES, iodoestradiol, progesterone, flutamide, bicalutamide, nilutamide and estramustine, and corticosteroids and said implants direct implantation to prostate saturates the tumor binding sites for said compositions to facilitate an effective method of concomitant hormonal and radiation treatment of early and advanced stage prostate cancers with minimal or no toxicity associated with such hormonal treatment.

65. A prostatic implant method and products of hormones and its derivatives of claim 64, wherein said tumor control is evidenced by tumor regression and return of pre-treatment elevated serum PSA to a low nadir value of less than 1 ng per ml and serum acid phosphatase to less than its upper normal limit value of 0.8 international unit.

66. A prostatic implant method and products of hormones and its derivatives of claim 64, wherein said hormonal implant preparation that lasts for five years is made to cost only one hundred dollars as against the cost of fifteen hundred dollars for the present commonly used LHRH analogue's 22.5 mg depot preparation that lasts for three months and thereby the estimated cost for five years LHRH analogue's use is 30,000 dollars as compared to this invention's implant preparation's cost of about hundred dollars for similar five year's treatment.

67. A method and product of claim 64, wherein said slow-release hormone implant treatment as hormonal prophylaxis against developing the prostate cancer in high risk group of men by slow release of androgen suppressive steroids from said hormone implants to the prostate in higher concentrations and their serum concentrations kept as low as just sufficient to suppress the androgen synthesis with none or minimal systemic toxicity and to follow up of any evidence of potential tumor development by periodic estimations of serum PSA and acid phosphatase which under said treatment will be at a low nadir